AMENDMENTS TO THE CLAIMS

1. **(Withdrawn)** An isolated recombinant human arginase I, comprising ubstantially the same amino acid sequence as set forth in SEQ ID NO: 9 and having a purity of 80-100%.

2. **(Withdrawn)** The recombinant human arginase I according to claim 1 further comprising six histidines attached to the amino terminal end thereof.

3. **(Withdrawn)** The recombinant human arginase I according to claim 1 having a specific activity of at least 250 I.U./mg.

4. **(Withdrawn)** The recombinant human arginase I according to claim 3 having a specific activity of 500 to 600 I.U./mg.

5. **(Withdrawn)** The recombinant human arginase I according to claim 4, comprising a modification that results in an *in vitro* plasma half-life of at least approximately 3 days.

6. **(Withdrawn)** An isolated recombinant human arginase I according to claim 1, having a purity of at least 90%.

7. **(Withdrawn)** The recombinant human arginase I according to claim 5, wherein said modification is pegylation.

8. **(Withdrawn)** The recombinant human arginase I according to claim 7, wherein said pegylation results from covalently attaching at least one polyethylene glycol (PEG) moiety to said arginase using a coupling agent.

9. **(Withdrawn)** The recombinant human arginase I according to claim 8, wherein said coupling agent is selected from the group consisting of 2,4,6-trichloro-s-triazine (cyanuric chloride, CC) and succinimide propionic acid (SPA).

10. **(Withdrawn)** A method of producing recombinant protein comprising:

(a) cloning a gene encoding said protein;

(b) constructing a recombinant *Bacillus subtilis* strain for expression of said protein;

(c) fermenting said recombinant *Bacillus subtilis* cells using fed-batch fermentation;

(d) heat-shocking said recombinant *Bacillus subtilis* cells to stimulate expression of said recombinant protein; and

(e) purifying said recombinant protein from the product of said fermentation.

11. **(Withdrawn)** The method according to claim 10 wherein said *Bacillus subtilis* is a prophage.

12. **(Withdrawn)** The method according to claim 10 wherein said protein is human arginase I.

13. **(Withdrawn)** The method according to claim 12 wherein said human arginase I comprises six histidines linked to the amino-terminus thereof, and said purifying step comprises affinity chromatography in a chelating column.

14. **(Withdrawn)** The method according to claim 12 wherein said fermenting step is performed using a feeding medium consisting essentially of 180-320 g/L glucose, 2-4 g/L $MgSO_4 \bullet 7H_2O$, 45-80 g/L tryptone, 7-12 g/L K_2HPO_4 and 3-6 g/L KH_2PO_4.

15. **(Withdrawn)** A pharmaceutical composition comprising an isolated and substantially purified arginase.

16. **(Withdrawn)** The pharmaceutical composition according to claim 15 wherein said recombinant human arginase is human arginase I.

17. **(Withdrawn)** The pharmaceutical composition according to claim 15 wherein said recombinant human arginase is human arginase I, further comprising six additional histidines attached to the amino terminal end thereof.

18. **(Withdrawn)** The pharmaceutical composition according to claim 15, wherein said composition is further formulated in a pharmaceutically acceptable carrier.

19. **(Withdrawn)** The pharmaceutical composition according to claim 15, wherein the formulation of said pharmaceutical composition is in a form suitable for oral use, for a sterile injectable solution or a sterile injectable suspension.

20. **(Withdrawn)** The pharmaceutical composition according to claim 16, wherein said recombinant human arginase I has a specific enzyme activity of at least 250 I.U./mg.

21. **(Withdrawn)** The pharmaceutical composition according to claim 20, wherein said recombinant human arginase I has a specific enzyme activity of 500 to 600 I.U./mg.

22. **(Withdrawn)** The pharmaceutical composition according to claim 16, wherein said recombinant human arginase I has a half-life in patient plasma of at least 3 days.

23. **(Withdrawn)** The pharmaceutical composition according to claim-22, wherein said recombinant human arginase I has a half-life in patient plasma of approximately at least 1 day.

24. **(Previously presented)** A method of treatment of human malignancies, comprising administering human arginase I.

25. **(Previously presented)** A method of treatment of human malignancies, comprising administering the pharmaceutical composition of claim 15.

26. **(Previously presented)** The method of claim 25, wherein said human malignancies are selected from the group consisting of: liver tumor, breast cancer, colon cancer and rectal cancer.

27. **(Previously presented)** A method of treatment of human malignancies comprising administering recombinant human arginase to a patient.

28. **(Previously presented)** A method of treatment of human malignancies in a patient comprising administering a pharmaceutical composition that reduces the physiological arginine level in said patient to below 10 μM for at least 3 days.

29. **(New)** The method of Claim 28, wherein said pharmaceutical composition comprises human arginase and wherein the composition is substantially free of a protein degradation inhibitor.

30. **(New)** A method of treatment of human malignancies, comprising:

administering arginase to a human patient; and

subsequently monitoring platelet count;

wherein an exogenously applied nitric oxide producer is not administered unless the levels of platelet count are below $50{,}000X10^9$.

31. **(New)** A method of treatment of human malignancies, comprising:

administering arginase to a human patient; and

subsequently monitoring prothrombin time;

wherein an exogenously applied nitric oxide producer is not administered unless a prothrombin time of 2X normal levels is not attained.

32. **(New)** A method of treatment of human malignancies, comprising:

administering a composition comprising arginase to a human patient, wherein said arginase is the sole active ingredient in said composition, whereby the arginine level in said patient is reduced to below 10μM for at least 3 days.

33. **(New)** A method of treatment of human malignancies comprising administering a recombinant pegylated human arginase I having an in vitro plasma half life of at least approximately 3 days to a human having a malignancy.

34. **(New)** A method of treatment of human malignancies comprising administering human arginase as the sole active agent to a human having a malignancy, wherein arginine levels in said human are maintained at or below 10μM for at least 3 days.